



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Office of the Secretary**

Posting of the National Security Presidential Memorandum 14, “Support for National Biodefense”

**ACTION:** Notice.

**SUMMARY:** National Security Presidential Memorandum 14 directs implementation of the National Biodefense Strategy. The Secretary is authorized and directed to publish the Memorandum in the *Federal Register*.

**DATES:** National Security Presidential Memorandum 14 was signed on September 18, 2018.

**FOR FURTHER INFORMATION CONTACT:** Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201; Telephone: 202-205-2882.

### **SUPPLEMENTARY INFORMATION:**

**NATIONAL SECURITY PRESIDENTIAL MEMORANDUM:** Support for National Biodefense

Memorandum for: The Vice President; The Secretary of State; The Secretary of the Treasury; The Secretary of Defense; The Attorney General; The Secretary of the Interior; The Secretary of Agriculture; The Secretary of Commerce; The Secretary of Labor; The Secretary of Health and Human Services; The Secretary of Transportation; The Secretary of Energy; The Secretary of Veterans Affairs; The Secretary of Homeland Security; Assistant to the President and Chief of Staff; Administrator of the Environmental Protection Agency; Director of the Office of Management and Budget; The Representative of the United States to the United Nations;

Director of National Intelligence; Assistant to the President for Science and Technology and Director of the Office of Science and Technology Policy; Chairman of the Joint Chiefs of Staff; Administrator of the United States Agency for International Development; Director of the Federal Bureau of Investigation.

It is a vital interest of the United States to prepare for, counter, respond to, and recover from biological incidents at home and abroad. Nearly all executive departments and agencies (agencies) contribute to the biodefense mission of the United States Government. Those contributions occur through a variety of authorities and programs. To ensure an integrated, comprehensive approach, agencies shall coordinate and manage biodefense activities in support of the broader biodefense enterprise, which consists of all stakeholders with a role in the detection of, prevention of, preparedness for, response to, and recovery from biological incidents, including Federal, State, local, tribal, and territorial governments, the private sector, and international partners.

Section 1. Policy. (a) It is the policy of the United States to preserve our national and economic security by protecting the Nation from biological threats. Acting within the biodefense enterprise, the United States Government will undertake actions at home and with partners abroad to reduce the risk of natural, accidental, and deliberate biological threats to humans, animals, agriculture, and the environment that have the potential to significantly affect the national and economic security of the United States.

(b) The foundation for the United States Government's role in the biodefense enterprise is the National Biodefense Strategy and its implementation plan (Strategy), which serve as the

authoritative sources for the goals, objectives, and definitions for United States Government activities in support of the broader biodefense enterprise. Agency biodefense activities shall be conducted consistent with section 1086 of the National Defense Authorization Act for Fiscal Year 2017 and the Strategy, including activities undertaken to implement prior Executive Orders and Presidential Directives, such as Homeland Security Presidential Directive (HSPD)-5 of February 28, 2003 (Management of Domestic Incidents); HSPD-9 of January 30, 2004 (Defense of United States Agriculture and Food); HSPD-18 of January 31, 2007 (Medical Countermeasures against Weapons of Mass Destruction); HSPD-21 of October 18, 2007 (Public Health and Medical Preparedness); Executive Order 13676 of September 18, 2014 (Combating Antibiotic-Resistant Bacteria); and Executive Order 13747 of November 4, 2016 (Advancing the Global Health Security Agenda To Achieve a World Safe and Secure From Infectious Disease Threats).

Sec. 2. Implementation. The policy set forth in section 1 of this memorandum shall be implemented, to the extent permitted by law and available appropriations, and subject to the internal programmatic and budgetary processes of the agencies, as follows:

(a) Consistent with the Strategy, the heads of agencies shall:

(i) prioritize the implementation of the Strategy and include Strategy-related activities within their strategic planning and budgetary processes;

(ii) coordinate their biodefense policies with other agencies that have responsibilities or capabilities pertaining to biodefense, as well as with appropriate non-Federal entities;

(iii) share information, as appropriate, and coordinate decision-making related to the biodefense enterprise; and

(iv) monitor, evaluate, and hold their agencies accountable for implementation of the Strategy.

(b) The Assistant to the President for National Security Affairs (APNSA) shall serve as the lead for policy coordination and review, acting through the process described in National Security Presidential Memorandum (NSPM)-4 of April 4, 2017 (Organization of the National Security Council, the Homeland Security Council, and Subcommittees), to provide strategic input and facilitate policy integration for Federal biodefense efforts.

(c) There is hereby established a Biodefense Steering Committee (Committee), which shall be chaired by the Secretary of Health and Human Services (Secretary). The other members of the Committee shall include the Secretary of State, the Secretary of Defense, the Attorney General, the Secretary of Agriculture, the Secretary of Veterans Affairs, the Secretary of Homeland Security, and the Administrator of the Environmental Protection Agency. The heads of other agencies with responsibilities or capabilities pertaining to biodefense shall participate at the invitation of the Committee, as appropriate. The Committee shall be responsible for monitoring and coordinating the implementation of the Strategy. The Committee shall seek consensus, with disagreements being addressed through the NSPM-4 process. The Committee may establish appropriate consultative or advisory mechanisms to facilitate interaction with non-Federal stakeholders. The Secretary, as the Chair of the Committee, shall serve as the Federal lead in coordinating implementation of the Strategy.

(d) To assist the Committee in carrying out the responsibilities described in subsection (c) of this section, the Secretary shall, within 90 days of the date of this memorandum, establish a Biodefense Coordination Team (Team) administratively located within the Department of Health and Human Services.

(i) The Secretary shall designate a senior official of, or detailed to, the Department of Health and Human Services to serve as the director of the Team, who shall report to the Secretary.

(ii) The Secretary, the Secretary of State, the Secretary of Defense, the Attorney General, the Secretary of Agriculture, the Secretary of Veterans Affairs, the Secretary of Homeland Security, the Administrator of the Environmental Protection Agency, and the heads of other agencies with responsibilities or capabilities pertaining to biodefense shall support the work of the Team, including, where appropriate, through the detail of personnel to the Team, consistent with law.

(iii) The Secretary, in consultation with the Committee, shall ensure that appropriate resources are provided by the Department of Health and Human Services to facilitate the Team's activities.

(iv) The Team shall, in consultation with existing governance bodies with responsibilities or capabilities pertaining to biodefense, assist the Committee in monitoring and coordinating implementation of the Strategy. The Team may convene working groups with relevant agencies as appropriate. In addition, the Team shall, on an ongoing basis,

maintain awareness of biodefense activities conducted by agencies, relevant interagency entities, and non Federal partners in the broader biodefense enterprise, including relevant private sector stakeholders. The Team shall identify opportunities to increase coordination with non-Federal partners, including international organizations. Subject to the approval of the Committee, the Team shall establish policies, processes, and procedures to govern its activities.

(v) The Secretary shall notify the APNSA when the Team is established.

(e) To ensure effective implementation of the Strategy, within 30 days of the formation of the Team and annually thereafter in alignment with the annual budget process, the Secretary shall submit written requests for information to the heads of agencies identified by the Committee as having responsibilities pertaining to biodefense (Covered Officials), including the following:

(i) the Secretary of State;

(ii) the Secretary of the Treasury;

(iii) the Secretary of Defense;

(iv) the Attorney General;

(v) the Secretary of the Interior;

(vi) the Secretary of Agriculture;

(vii) the Secretary of Commerce;

(viii) the Secretary of Labor;

(ix) the Secretary of Health and Human Services;

(x) the Secretary of Transportation;

(xi) the Secretary of Energy;

(xii) the Secretary of Veterans Affairs;

(xiii) the Secretary of Homeland Security;

(xiv) the Administrator of the Environmental Protection Agency;

(xv) the Director of National Intelligence;

(xvi) the Administrator of the United States Agency for International Development; and

(xvii) the Director of the Federal Bureau of Investigation.

(f) These requests shall ask how agency programs and activities contribute to the objectives of the Strategy. Covered Officials shall respond to these requests within 60 days of receipt of the request through a Biodefense Memorandum, as described in paragraphs (i)-(ii) of this subsection.

(i) The Biodefense Memorandum shall identify those activities, programs, and projects that are planned, programmed, or have been executed that advance or are expected to advance the Strategy; quantify, to the extent feasible, resources allocated to biodefense within the agency; assess the extent to which the goals, objectives, and sub-objectives of the Strategy are being met; and identify impediments to timely and effective implementation and options for their resolution. Each agency shall provide its Biodefense Memorandum to the Committee, the Team, the National Security Council (NSC) staff, and the Office of Management and Budget (OMB). The Team shall distribute the collected Memoranda to Covered Officials.

(ii) Covered Officials are not required to provide information on specific law enforcement activities, counterproliferation activities, military plans or operations, intelligence activities, or criminal investigations.

(g) The Team, as informed by each Biodefense Memorandum and consultations with the agencies, shall prepare a Biodefense Assessment (Assessment) to identify any gaps, shortfalls, and redundancies; describe any challenges to the implementation and execution of the Strategy; and recommend any necessary updates or changes to the Strategy. The Assessment shall include an analysis of the extent to which current United States Government resources support the goals and objectives of the Strategy, how existing programs and resources could be better executed or allocated to align with the Strategy, and how additional resources could, if available, be applied to support the goals of the Strategy. The Team shall coordinate the Assessment with the NSC staff and the OMB prior to its finalization. The Assessment shall be submitted to the Committee



for approval and provided to the APNSA and the Director of the OMB within 180 days of the formation of the Team and annually thereafter.

(h) Each year, within 90 days of the approval of the Assessment, the Team shall summarize the Assessment and prepare, subject to the approval of the Committee and in coordination with the NSC staff, a public report describing the actions taken to reduce the risk of biological threats to the American people.

(i) Each year, Covered Officials, in coordination with the APNSA through the NSPM-4 process, shall prepare joint policy guidance (Guidance) on priority areas of biodefense. The Guidance shall be informed by the Assessment, and Covered Officials shall consider the Guidance when they develop their annual budget requests. Based on the Guidance, the Covered Officials shall include in their respective annual budget requests to the OMB information on the programs within the budget requests that support the implementation of the Strategy and conform to budget formulation requirements established by the OMB, including specified funding levels.

Concurrently, Covered Officials shall submit a memorandum to the NSC staff and the OMB conveying their response to the policy Guidance. Covered Officials shall ensure that new and existing activities are prioritized and can be accommodated within budget guidance from the OMB.

(j) Within 120 days of the issuance of this memorandum, the Team, in coordination with the NSC staff through the NSPM-4 process, shall develop a proposal for metrics, milestones, end states, and roles and responsibilities of agencies, with respect to biodefense activities,

particularly in meeting the goals, objectives, and sub-objectives of the Strategy. This proposal will be approved by Deputies, consistent with the NSPM-4 process.

(k) Within 2 years of the date of this memorandum, and every 2 years thereafter, Covered Officials shall review and, as appropriate, revise the Strategy. The APNSA, acting through the NSC staff, shall coordinate the development of updates to the Strategy. The updates to the Strategy shall be submitted to the President through the APNSA and, to the extent permitted by and consistent with applicable law and policy, released to the public.

(l) The APNSA, with the approval of every member of the Committee, may designate a different member of the Committee to serve as Chair of the Committee and perform the responsibilities specified in subsection 2(c).

Sec. 3. Earlier Presidential Actions. (a) Presidential Policy Directive-2 of November 23, 2009 (Implementation of the *National Strategy for Countering Biological Threats*) and HSPD 10/National Security Presidential Directive-33 of April 21, 2004 (National Policy for Biodefense) are hereby superseded and replaced.

Sec. 4. General Provisions. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof;
- or

(ii) the functions of the Director of the OMB relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable laws and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Secretary is hereby authorized and directed to publish this memorandum in the *Federal Register*.

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Alex M. Azar II  
Secretary

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Dated: October 12, 2018.

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